



Patent
Attorney's Docket No. 017753-154

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:)
Therese de BIZEMONT *et al.*) Group Art Unit: 1635
Application No.: 09/836,439) Examiner: Richard A. Schnizer
Filed: April 17, 2001) Confirmation No.: 5851
For: GENE THERAPY WITH CHIMERIC)
OLIGONUCLEOTIDES DELIVERED)
BY A METHOD COMPRISING A)
STEP OF IONTOPHORESIS)

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RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Response to Restriction Requirement is in complete response to the Official Action (Restriction Requirement) mailed on December 24, 2002 (Paper No. 16). A one-month Extension of Time is included, extending the due date to February 24, 2003.

The Examiner has required the election of a single Group, to which the claims will be restricted if no generic claim is held to be allowable. Applicants hereby elect, with traverse, Group I (*i.e.*, claims 1-18, 20, 21, 30, and 39), drawn to methods of delivering an oligonucleotide for reversion of a K296E mutation in human RP1 *in vivo* to cells of an animal by iontophoresis.

Turning now to the restriction requirement, Applicants respectfully traverse. For the reasons set forth below, Applicants request that the restriction requirement be modified so that the inventions of Groups I-XII will be examined together.

Under M.P.E.P. § 803, a restriction is proper if the subject matter can be restricted into one of two or more claimed inventions, and these inventions are either independent (M.P.E.P. § 806.04) or distinct (M.P.E.P. § 806.05). However, the second element for a restriction requirement to be proper is that if the search and examination of an entire application can be made without serious burden, the Examiner *must* examine it on the merits, even though it includes claims to independent and distinct inventions.

Applicants submit that Groups I-XII are not independent and distinct, as all of the claims of the present invention share the essential characteristic of the ability to transfer chimeric oligonucleotides into target cells via iontophoresis. Applicants note, however, that none of the Groups of the present restriction requirement, mail dated December 24, 2002, relate to a general method of transferring, *in vivo*, chimeric oligonucleotides into target cells of animal or human tissue via iontophoresis, as set forth in claim 1, steps a) and b) of the present invention. Instead, each Group is specifically directed to one type of mutation.

Thus, if the Examiner will not rejoin all of the Groups, Applicants request that the claims directed to methods of delivering an oligonucleotide *in vivo* to cells of an animal by iontophoresis be examined (as set forth in the Restriction Requirement of September 24, 2002, paper no. 14, as Group I.

Further, Applicants submit that a search of each Group as set forth in the outstanding Office Action would not be burdensome to the Examiner. All of the claims relate to chimeric oligonucleotides delivered via iontophoresis. A search for those claims directed to the chimeric oligonucleotide would overlap a search for claims directed to methods of using these name oligonucleotides.

Furthermore, the Office has not set forth an explanation of how a search of the claimed invention would be burdensome. Accordingly, Applicants assert that a proper restriction under M.P.E.P. § 803 has not been set forth with regard to the originally presented claims. The restriction should be withdrawn or, at the very least, reconsidered.

Withdrawal of the restriction requirement and rejoinder of the claims of Groups I-XII, and further and favorable consideration of all the claims of record on the merits is respectfully requested.

CONCLUSION

Applicants submit that the present application is fully in condition for examination. An early examination on the merits is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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